

REMARKS

Status of the Claims.

Claims 19, 20, 22, 23, 30-38, and 46-50 are pending with entry of this amendment, claims 1-18, 21, 24-29, 39-45, and 51-93 being cancelled and no claims being added herein. Claims 19, 22, 23, 35, 38, 46-50 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (*e.g.*, in the claims as originally filed).

Election/Restriction.

Pursuant to a restriction requirement made final, Applicants cancel non-elected claims 39, and 67-83 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Claim Objections.

Claims 4, 23, 38, and 55 were objected to because they recite non-elected species, including clioquinol, deferiprone, and pseudan." Applicants traverse.

The Examiner is reminded that the election of desferrioxamine is **an election of species.** As stated in M.P.E.P. §809.02(c) if there is a generic claim, the Examiner is to include "a complete action on the merits of all the claims readable on the elected species. In the instant case, claims 4, 23, 38, and 55 all read on the elected species as a member of a Markush group. There is consequently, no requirement that Applicants amend these claims to recite a single species. Accordingly, this objection should be withdrawn.

The Examiner indicated that should claims 19-23, and 30-34 be found allowable, claims 52-55, and 62-66 would be objected to as allegedly being a substantial duplicate. Applicants note that claims 52-55 and 62-66 are canceled herein thereby obviating this objection.

The Examiner indicated that should claims 30-34 be found allowable, claims 46-50 would be objected to under 37 C.F.R. §1.75 as allegedly being a substantial duplicate thereof.

The Examiner is reminded that claims 30-34 ultimately depend from claim 19 and thereby incorporate all the elements of claim 19, while claims 46-40, as amended herein, ultimately depend from claim 35 and thereby incorporate all the elements of claim 35. Claim 19 is directed to a method of "inhibiting the progression of a disease characterized by neural degeneration in a mammal",

while claim 35 is directed to a method of “mitigating one or more symptoms of a disease characterized by neural degeneration in a mammal”. The claims are clearly not substantial duplicates of each other and accordingly the objection should be withdrawn.

35 U.S.C. §112, first paragraph, enablement.

Claims 1-6, 14-23, 30-38, 40, 46-55, and 62-66 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for administration of desferrioxamine to an animal, allegedly does not reasonably provide for enablement for upregulation of endogenous ferritin or hemoglobin, or for administration of derivatives as broadly claimed. Applicants traverse by argument and amendment.

The claims, as amended herein are directed to methods that involve “. . . administering to a mammal having said disease, an agent that binds or chelates free iron. . . “ (claim 19) or . . . administering to said mammal having said disease an agent that causes the sequestration or chelation of free iron . . . “ (claim 35).

The claims, as amended, do not reference “derivatives”, or upregulation of endogenous ferritin or hemoglobin.

Accordingly the rejection under 35 U.S.C. §112, first paragraph, on these grounds should be withdrawn.

35 U.S.C. §112, first paragraph, written description.

Claims 1-6, 4-23, 30-38, 40, 46-55, and 62-66 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner objected to the use of the term “derivatives” in claims 4, 23, 38, and 55.

The term “derivatives” is eliminated in the claims as amended herein. Accordingly the rejection of claims 1-6, 4-23, 30-38, 40, 46-55, and 62-66 under 35 U.S.C. §112, first paragraph, on these grounds should be withdrawn.

35 U.S.C. §102.

Claims 1-4, 6, 16-23, 32-38, 40, 48-55, and 64-66 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ben-Shachar *et al.* (1991) *J. Neurochemistry*, 56: 1441-1444. Applicants traverse.

Independent claims 19 and 35, as amended herein, are directed to methods that involve administering to a mammal having a disease characterized by neural degeneration an agent that sequesters or chelates free iron:

19. A method of inhibiting the progression of a disease characterized by neural degeneration in a mammal, said method comprising:

administering to a mammal having said disease, an agent that binds or chelates free iron in an amount sufficient to reduce free iron levels in a neural tissue of said mammal.

35. A method of mitigating one or more symptoms of a disease characterized by neural degeneration in a mammal, said method comprising administering to a mammal having said disease an agent that causes the sequestration or chelation of free iron in said mammal in an amount sufficient to reduce free-iron levels in a neural tissue of said mammal and thereby to mitigate one or more symptoms of said disease.

In contrast, Ben-Shachar *et al.* discloses a series of experiments that involve administering desferrioxamine to rats that were injected with 6-hydroxydopamine (6-OHDA) to induce dopaminergic neuronal lesions:

Rats were anesthetized with a mixture of 15 mg/kg of pentobarbital and 60 mg/kg of chloral hydrate. 6-OHDA (250 µg in 25 µl of 0.9% NaCl containing 0.2% ascorbic acid), desferrioxamine mesylate (Desferral: 130 ng in 25 µl), a combination of both (Desferral 5 min before 6-OHDA), or saline (25 µl) was injected into the left cerebral ventricle using stereotactic techniques (Ungerstedt, 1968, Uretsky and Iversen, 1970). [emphasis added] (page 1442, col. 1)

Ben-Shachar *et al.* simply does not disclose administration of a sequestering or chelating agent to a mammal having a disease as recited in the presently pending claims. Accordingly, Ben-Shachar *et al.* fails to provide all the elements of the presently pending claims and the rejection under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Claims 1-4, 6, 14-15, 18-23, 30-31, 33-38, 40, 46-47, 49-55, 62-63, and 65-66 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Brown *et al.* (U.S. Patent 5,849,290).

Brown *et al.* does not teach the administration of a chelating agent to reduce the levels of free iron in a neural tissue. Indeed, the reference fails to teach the desirability of free-iron chelation as a treatment method.

With respect to the Examiner's assertion regarding inherency, the Examiner is reminded that anticipation by inherency requires that: 1) the missing descriptive matter be "necessarily present" in the prior art reference and that 2) it would be so recognized by persons of ordinary skill in the art.

Continental Can Co. v Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)

In the instant case, Brown *et al.* does not disclose or otherwise teach or suggest the chelation/sequestration of free iron to treat a disease characterized by neural degeneration. To the contrary, Brown *et al.* simply generically describes the use of chelating agents without specific reference to iron chelation. Moreover, the use of chelators is optional, prophetic, and no dosages are provided. There is no actual demonstration of a treatment utilizing chelators.

Consequently, the use of a chelator "in an amount sufficient to reduce reducing free iron levels in a neural tissue of a mammal" as recited in the presently pending claims is not necessarily present in the disclosure provided by Brown *et al.* Moreover, as Brown *et al.* offers no disclosure regarding the reduction of free iron in neural tissues, one of skill in the art would not recognize such an element in the Brown *et al.* disclosure.

Accordingly, Brown *et al.* fails to meet the requirements for anticipation or for anticipation by inherency. Accordingly the rejection under 35 U.S.C. §102(b) in light of Brown *et al.* should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

QUINE INTELLECTUAL PROPERTY LAW
GROUP, P.C.
P.O. BOX 458
Alameda, CA 94501
Tel: 510 337-7871
Fax: 510 337-7877

Respectfully submitted,



Tom Hunter
Reg. No: 38,498

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